4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1205]

Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Accessible Standardized Medical Device Labeling." The purpose of this public workshop is to discuss the growing need for medical device labeling to be delivered in a clear, concise, and readily accessible format so that patients, caregivers, and healthcare providers may access and utilize device labeling as efficiently and effectively as possible. This public workshop aims to engage stakeholders in active discussion with FDA and to encourage public comments regarding standard content and format for medical device labeling and the use of a repository containing medical device labeling.

DATES: The public workshop will be held on April 29, 2013, from 8 a.m. to 5 p.m. and April 30, 2013, from 8 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT:

Mary Weick-Brady,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 5426,

301-796-6089,

FAX: 301-847-8510,

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SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by April 5, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Joyce Raines by email: Joyce.Raines@fda.hhs.gov or phone: 301-796-5709 at least 7 days prior to the public workshop.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. Select

this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Mary Weick-Brady to register (see FOR FURTHER INFORMATION CONTACT). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by April 5, 2013, 5 p.m. EST. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after April 5, 2013. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration, you may indicate if you wish to present during a public comment session and which topics you want to address. All topic-focused sessions will be held during the general session. Standard content and format of full labeling and a shortened version of labeling will be addressed on the first day. The labeling repository will be discussed in a focused session on the second day. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public

comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 12, 2013. All requests to make oral presentations must be received by the close of registration on April 5, 2013, at 5 p.m. If selected for presentation, any presentation materials must be emailed to Mary Weick-Brady (see FOR FURTHER INFORMATION CONTACT) no later than March 29, 2013. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain information on medical device labeling. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is April 12, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to http://www.regulations.gov or written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

I. Background

Currently, there are no regulations that explicitly define and describe a standard content and format for medical device labeling. FDA is concerned that the lack of standard content and format may translate into an increased risk of medical device error. Also, there is no single available source of medical device labeling for people to view, search, and download for devices that are used in clinical and non-clinical environments. FDA is aware of and concerned with the risk of medical errors that result from lost or inaccessible labeling.

FDA conducted a two-phase research study with Research Triangle Institute (RTI) focusing on healthcare professionals and their experiences with medical device labeling, and what they would want in a standard version of device labeling. Key findings from the survey helped create an outline for standard content and format for medical device labeling identifying the most relevant sections. Participants also expressed the need for a condensed version of labeling to act as a quick reference for safe and effective use of devices. Participants indicated that having a “quick guide” describing proper device operation and use would be more

convenient and effective with the option of referring to a more comprehensive form of labeling should it be required.

FDA also conducted a survey with the National Family Caregivers Association (NFCA) on medical device labeling to elicit home caregivers' experiences with medical device labeling for devices that are used in the home. Respondents indicated what sections of medical device labeling they believed would be most important when operating or troubleshooting a device in the home care environment. Respondents also stated they would like a standard content and format of labeling with access to a "quick guide" for proper instructions for use. The majority of respondents stated they would make use of a searchable Web site that contained labeling for medical devices.

Accessible labeling has been a growing problem for healthcare professionals who operate medical devices, lay caregivers, and patients themselves. As more medical devices migrate out of clinical care environments and into patients' homes, the assurance that devices are being used properly and safely no longer resides with a healthcare professional; rather, the responsibility is with the patient, spouse, sibling, or even children. When medical devices are sent home with patients or are moved from one location to another, the labeling often becomes misplaced, lost, damaged, or discarded, which may result in adverse events or other complications due to misinterpretations and absence of proper labeling.

FDA is holding this public workshop to address these growing concerns and to solicit responses from the medical devices industry, healthcare practitioners, caregivers, and patients regarding a standard content and format of medical device labeling and methods to make medical device labeling accessible and searchable while keeping patient safety a priority.

II. Topics for Discussion at the Public Workshop

The workshop sessions will focus on the following general topics:

A. Summary of FDA Work on Labeling

1. RTI two–phase research study of healthcare professionals regarding device labeling.
2. NFCA survey of consumers on medical device labeling.
3. Cooperative Research and Development Agreement with Kwikpoint for the development of visual language for device labeling.
4. The Center for Drug Evaluation and Research measures of success with standard labeling and the use of a drug repository.

B. Standard Content and Format of Device Labeling

1. Review the outline for a draft standard content and format of medical device labeling.
2. Current thinking on a standard content and format of medical device labeling.
3. Use of symbols in medical device labeling.
4. Discuss a shortened version of standard medical device labeling.

C. Repository of Medical Device Labeling for Home Use Devices

1. Online access to device labeling.
2. Panel discussions on using an online device labeling site.
3. Discuss the types of devices whose labeling should be on the site.

Dated: December 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-00003 Filed 01/04/2013 at 8:45 am; Publication Date: 01/07/2013]